

Chapter 5

Design

Learning Objectives

At the conclusion of this chapter, the reader will be able to

- Ensure interoperability of software, hardware, network components and medical devices
- Ensure compliance with applicable industry, regulatory and organizational standards
- Ensure a process exists to incorporate industry, technology, infrastructure, legal and regulatory environment trends
- Design an information infrastructure that supports current and anticipated business needs (e.g., business continuity, disaster recovery)
- Evaluate existing and emerging technologies to support organization's future growth and strategy
- Employ and implement effective data management using an established data governance protocol

Introduction

The *Dictionary of Computing* defines *system design* as “the activity of proceeding from an identified set of requirements for a system to a design that meets those requirements.”¹ System design depends upon the definition of *system*, which, according to the *Oxford English Dictionary*, means “a set or assemblage of things connected, associated, or interdependent, so as to form a complex unity.”² Healthcare information technology (HIT) systems today take that complexity to a new level in function and interoperability. These systems must support advanced clinical functionality, patient accounting and financial accounting and have been

doing this for years. The systems must also support functionality demanded by new healthcare regulations, medical devices, mergers and acquisitions, as well as address changes and advances in the information technology (IT) industry.

Compatibility and interoperability are two key aspects of system design. Considering the complexity and criticality of enterprise IT systems in healthcare, it is essential to ensure any new medical devices, software, hardware, or network components are compatible and interoperable.

Compliance with applicable industry, regulatory and organizational standards is a fundamental aspect of system design. Healthcare organizations could face severe implications for not adhering to these standards. A key best practice in system design is the development of a comprehensive technical specification. The design team documents design specifications regarding the infrastructure, network, security, application and use cases based on the requirements uncovered during system analysis. For more information on defining and prioritizing system requirements, refer to [Chapter 4](#) “Systems Analysis.”

Compatibility and Interoperability of System Components

Any healthcare enterprise today owns and continually purchases a plethora of hardware, software, network components and medical devices. The hardware may include laptop computers, servers, mobile devices and tablets, each running its own operating system (OS) that is not necessarily compatible with other operating systems. The application software that runs on these devices serves a variety of purposes from patient accounting to payroll, laboratory, pharmacy, radiology, dietetics, digital pathology and so on. Network components include routers (wired and wireless), firewalls, cabling and Internet connectivity. Networks today must support connectivity of devices within the enterprise as well as Wi-Fi access for patients and visitors. Medical devices such as ultrasounds, magnetic resonance imaging (MRIs), patient monitors, ventilators and even blood pressure cuffs all provide information digitally and must connect to the network as well. For more information on hardware, software and networks, refer to [Chapter 2](#), “Technology Environment.”

Organizations should define a process by which the IT department reviews purchases of any of these components for compatibility and interoperability. Remember that not all devices or software will work out of the box. There may be system upgrades involved to incorporate the device onto the network. For example, a new patient monitor may connect to the existing network from a physical standpoint, but may not be compatible with the existing patient monitoring system used to aggregate and distribute waveform data to the electronic health record (EHR). This process dictates close cooperation between the IT department and the procurement/purchasing department so IT has a chance to review purchases, thus avoiding such hidden costs of system and/or device upgrades and potential delays.

Compatibility of medical devices and systems is just one dimension of systems design. Interoperability is equally important. HIMSS defines interoperability as “the ability of different information systems, devices, or applications to connect, in a coordinated manner, within and across organizational boundaries to access, exchange and cooperatively use data amongst stakeholders, with the goal of optimizing the health of individuals and populations.”³ In the patient monitor example above, interoperability may translate to a Health Level Seven (HL7®) interface to the patient monitor to enable admissions, discharges and transfers (ADT) notifications from the existing EHR system.

Standards Compliance

Healthcare providers face a huge number of external standards from government and industry, in addition to their own internal standards. Some of these affect the entire organization, and others affect just one department. Some countries even dictate which vendor IT system the organization must purchase. ASTM International, HL7, Digital Imaging and Communications in Medicine (DICOM®), and other international organizations publish many standards related to healthcare IT. The Institute of Electrical and Electronics Engineers (IEEE) publishes standards for wired and wireless networking used by most countries in the world. Just as an enterprise must have a process to address compatibility of system components, it must also develop a process to address standards compliance. Given the number of standards, this is not a simple effort. There must be an overlap between business process and compliance management. System design should attempt to address standards by the clear definition of technical specifications.

Process to Address Industry Trends

With the extensive changes occurring in healthcare and technology, a process must exist or be created to evaluate and incorporate industry, technology, infrastructure, legal and regulatory trends. This process must address areas that in the past were governed by departments other than IT. The digitization of telephone systems means that these systems generally share the same networks as IT and have become a part of the IT organization. Medical devices such as electrocardiographs, ultrasound and MRI devices now generate millions of bytes of medically relevant data and must be integrated into the electronic patient record. The purchase of such devices must include IT participation to ensure compatibility and interoperability with existing systems.

One of the most critical trending issues facing healthcare IT is cybersecurity. The greatest threat to healthcare networks comes from medical devices. Many computerized medical devices connect to hospital enterprise networks. In the

development of these medical devices, enterprise security was not included in the product requirements. In many cases, generally accepted IT security practices like anti-virus software, firewall software and frequent password changes are not compatible with medical devices or the medical devices have significant restrictions on the use of these generally accepted security practices and tools. For example, some medical device vendors discourage customers from using anti-virus software to scan files associated with medical devices. Other medical device vendors hard-code passwords or use obsolete commercial operating systems.

Many healthcare organizations have invested in Innovation Centers within their organization to develop and deploy healthcare technology innovations. An example of this is the Emory Healthcare Innovation Hub (<https://www.emoryhub.com>). “The Emory Healthcare Innovation Hub is a premier health care advancement and commercialization program that connects all the pieces of the health care continuum to validate, accelerate and realize ideas. Our mission-realize improvements in health outcomes, increase access to quality care, lower overall costs to the system and improve health care provider experiences in Georgia and across the nation.” These innovation centers are developing solutions to address problems in the dynamic healthcare environment.

Structure of the System Design Team

The members of the system design team may vary based on the complexity and scope of the project. A project sponsor, one of the team’s key members, should kick off the project with the team and help determine the business goals and how those goals should be measured. Once the team has been established and the goals clearly defined, the sponsor may not need to be involved in more detail-oriented design meetings. Below is a list of potential team members:

- Project sponsor
- Project manager
- Solution architect⁴
- Enterprise business architect⁴
- Biomedical engineers
- Application developers
- Quality assurance analysts
- Information security officer
- Stakeholders/users

Detailed Technical Specifications

The design team must create comprehensive and detailed technical specifications that not only cover the function of the system or applications, but also address

nonfunctional issues, such as information infrastructure. Some of the key areas of technical specifications that should be addressed are:

- System and wired/wireless network architecture—Does the system have to fit into the organization's existing architectures or may it vary?
- Security and data encryption—Does the system integrate into the organization's security standards?
- Disaster recovery—What is the recovery time objective (RTO) or the time it will take to recover the system in a disaster? What is the recovery point objective (RPO) or to what point in time must the system be restored?
- Data conversion—What are the data conversion options if converting from one system to another with different data models?
- Response times—What are the expected response times and how will they be measured?
- System backups—What are the backup options? How long will backups run?
- System monitoring—How will the system be monitored? Will it fit into the organization's existing monitoring infrastructure?
- Change management—How does the vendor of a newly purchased system handle changes? Is there a regular schedule? Or, is it done at customer convenience?
- Availability—What are the availability requirements? What is the downtime associated with system upgrades?
- Time zone and daylight savings time support—Does the system support multiple time zones, especially if the organization has facilities in different time zones? Are system outages required for spring or fall clock changing?
- Standards—Does the system support integration standards such as HL7, International Statistical Classification of Diseases and Related Health Problems, 10th Revision (ICD-10) or DICOM?
- Government regulations—Does the system meet current government regulations? What is the vendor commitment for turnaround of new regulations?
- System integration—How will the system integrate with the other HIT systems and medical devices in the enterprise?
- Usability—Much focus is being placed on usability today, and that topic will be discussed in more detail below. Usability should include accessibility for persons with disabilities as well as the use of mobile devices.
- Workflow definitions—The definition of desired workflows is another key area of the design that will be discussed in more detail later in the chapter.
- Data management—Does the system fit the organization's data management policies and procedures for such functions as backup, recovery and archiving?
- Antivirus/OS patching policy—Which anti-virus application and versions are supported by the system? Is automated OS/security patching allowed?

Usability

As previously mentioned, interest in usability has grown significantly over the past decade due to increased EHR adoption. HIMSS has created various tools and forums to help clinicians and health IT professionals overcome some of the more common challenges with usability, including the Usability Maturity Model (UMM).⁵ IT examines three nonhealthcare usability models and uses common themes from those models to create a healthcare model with five phases:

- Phase 1: Unrecognized—lack of awareness of usability
- Phase 2: Preliminary—sporadic inclusion of usability
- Phase 3: Implemented—recognized value of usability and small teams using it
- Phase 4: Integrated—benchmarks implemented and have dedicated user experience team
- Phase 5: Strategic—business benefit well understood, mandated, budgeted and results used strategically in the organization

The UMM documents how an organization can take itself from one phase to another and recommends the following tactics to expand usability within the organization:

- Include usability in contracts
- Create feedback loops from users to vendors
- Talk about tasks and workflows
- Educate about return on investment related to usability
- Engage organizational leaders in usability
- Include usability metrics on one project
- Interview users to determine key usability issues
- Compile evidence from usability assessments
- Look for and document usability wake-up calls
- Find a business/organization driver supporting need for usability

Information Infrastructure

The information infrastructure must be able to support today's business requirements and anticipate emerging or future business requirements. A continuing trend, known as bring your own device (BYOD), is one example of a requirement prompted by doctors, nurses and other employees who want to use their own notebook computers, tablets or smartphones on the enterprise network. Most healthcare organizations have made investments in secure mobile communications platforms and network infrastructure to support a BYOD strategy. A good example of a future business requirement is the 11th Revision of the International Classification of Diseases (ICD-11).⁶ Most healthcare organizations today utilize ICD-10. While today's applications do

not support ICD-11, healthcare organizations should consider how new system/applications will support it the future. Overall, an organization should have a process in place to examine or evaluate emerging trends and technologies. This evaluation should be done on a regular basis as new technologies emerge or existing technologies begin to be adopted. As part of the process, the organization should decide where it wants to be on the technology adoption curve (Figure 5.1).

As more and more healthcare records are electronic, business continuity emerges as a key part of the IT infrastructure. Organizations must plan for various types of disasters, whether natural or man-made. Off-site storage of data becomes a minimal requirement. Many sites negotiate contracts with disaster recovery vendors to retain not only copies of data, but also the capability to restore entire systems. Larger organizations may own multiple data centers in which they may mirror their data. Networks must be in place to access these remote sites. The business continuity plan must not only ensure that the remote sites are in place, but also test the plan at frequent intervals to make certain that it can be executed.

Many healthcare organizations now utilize cloud-based applications, which enable on demand availability of computing resources. Cloud computing refers to the provision of applications over the Internet where customers do not have to invest in the hardware and software resource needed to run and maintain the applications. Of particular concern in healthcare, is the security of all application data and customer information. With cloud computing, data is stored on servers/infrastructure not owned by the healthcare organization. The security requirements of the healthcare organization need to be well understood by the cloud vendor and incorporated into the system design.⁷

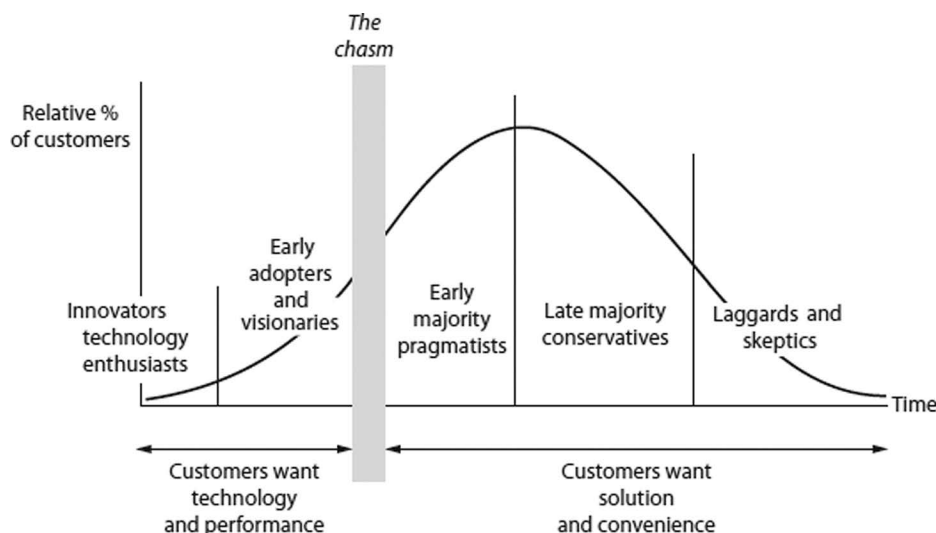


Figure 5.1 Technology adoption curve.

Data Management

Healthcare organizations must address a wide variety of issues related to their data. Data Management International (DAMA®) created a framework for data governance that defines 11 data management knowledge areas⁸:

1. Data Governance—planning, oversight and control over management of data and the use of data and data-related resources
2. Data Architecture—the overall structure of data and data-related resources as an integral part of the enterprise architecture
3. Data Modeling & Design—analysis, design, building, testing and maintenance
4. Data Storage & Operations—structured physical data assets, storage, deployment and management
5. Data Security—ensuring privacy, confidentiality and appropriate access
6. Data Integration & Interoperability –acquisition, extraction, transformation, movement, delivery, replication, federation, virtualization and operational support
7. Documents & Content—storing, protecting, indexing and enabling access to data found in unstructured sources (electronic files and physical records) and making this data available for integration and interoperability with structured (database) data
8. Reference & Master Data—Managing shared data to reduce redundancy and ensure better data quality through standardized definition and use of data values
9. Data Warehousing & Business Intelligence—managing analytical data processing and enabling access to decision support data for reporting and analysis
10. Metadata—collecting, categorizing, maintaining, integrating, controlling, managing and delivering metadata
11. Data Quality—defining, monitoring, maintaining data integrity and improving data quality

The organization must define a process for addressing those data management functions. Then, the system design team must ensure that the system fits into that process.

Summary

Successful system design centers on the design team, which must include the proper members. The design team should create clear, documented technical specifications. Two ways in which the design team can produce such requirements are by examining usability and data management. It is fundamental

that the system design ensures the compatibility and interoperability of medical devices, software and hardware components. The system must also comply with industry, regulatory and organizational standards. As healthcare practices are constantly changing and evolving, a process should be in place for evaluating emerging technologies to support the healthcare organization's strategy and mission.

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